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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,668	02/25/2005	Juergen Haecker	P70348USD	7646
136 7590 07/28/2009 JACOBSON HOLMAN PLLC 400 SEVENTH STREET N.W. SUITE 600 WASHINGTON, DC 20004				
EXAMINER				
MUI, CHRISTINE T				
ART UNIT		PAPER NUMBER		
1797				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/525,668

Applicant(s)

HAECKER ET AL.

Examiner

CHRISTINE T. MUI

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 12 May 2009 have been fully considered but they are not persuasive.

It is to be noted that all of applicants arguments pertain the injection molding limitation. In response to the applicant's argument that the rigid material and the flexible material in the disposable cassette are made by the process of a two-component injection molding and that is not disclosed in the references is acknowledged. However, injection molding is a process to which a product is made. The references directed to Anazawa and Saaski disclose the claimed limitation of the device itself (i.e. one integral part made from two separate parts. As the applicant has pointed out, the reference to Saaski, in column 24, lines 26-62, discloses that the substrate, the inlet cavity and channel, the outlet cavity and port as well as the regulator seat are manufactured by molding and machining processing and are to be bonded together as one piece by any suitable bonding materials, creating a leak proof device.

The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

With respect to the combination, applicants are not clearly arguing the examiners reasons for combining. In response to applicant's arguments against the references

individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-4, 7-10, 15-17 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 02/24320 to Anazawa et al in view of USP 5,660,728 to Saaski et al.(herein referred 'Saaski') .

5. USP 7,238,325 is an English Translation of WO 02/24320 and is used as the basis of the rejections.

6. Regarding claims 1-2, 4 and 9, the reference Anazawa discloses a micro chemical device with a valve function for which the pressure resistance is high and the channel cross sectional area does not depend on the fluid pressure. The micro chemical device is formed with a channel in one member that is bonded with another member as well as a cavity section formed as a portion of the channel in laminated members. The laminated members are from a flexible material with a specified tensile modulus of elasticity and compressing the cavity section from the outside of the member causes deformation in the flexible member. In an embodiment, the cavity is of a convex structures on the outer surface of the member and the flexible member may be constructed to be of a medium hard material surrounding the region of the cavity and of a soft material with a lower tensile modulus of elasticity at the corresponding position of the cavity section for deforming (see abstract, column 1, lines 61-column 2, line 49). It is interpreted by the examiner that the members that are bonded together are bonded in a sealing manner and the flexible material that the laminated members are formed from is of a single piece as seen in Figure 1A. Furthermore, it is interpreted by the

examiner that where the cavity section is of a convex structure formed on the flexible material to identify the corresponding cavity section is considered to be an engagement region. Anazawa does not disclose the member is made of an injection molding technique, but Saaski discloses a fluid handling device for handling continuous fluid flow rates in a device that comprises of a substrate made of a durable material in which the channel and cavities are made of such as molding (see abstract, column 24, lines 56-64). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the layer that covers the channels to be made of a well known manufacturing technique, such as injection molding so that the second part can be easily made of a single piece and be cost efficient.

7. Regarding claims 3 and 8, the references Anazawa and Saaski disclose the claimed invention. Anazawa discloses channels formed between two members formed from a flexible material with a specified tensile modulus of elasticity (see column 1, lines 61-column 2, line 3).

8. Regarding claims 7 and 15-17, the references Anazawa and Saaski disclose the claimed invention. Anazawa discloses the micro channel device has a channel formed between two members with a width from 1 to 1000 micrometers and a height from 1 to 1000 micrometers and a cavity section formed as a portion of the channel. In an embodiment, the cavity is of a convex structures on the outer surface of the member and the flexible member may be constructed to be of a medium hard material surrounding the region of the cavity and of a soft material with a lower tensile modulus of elasticity at the corresponding position of the cavity section for deforming, which is

considered an engagement region. Furthermore, in an embodiment, the cavity section is from 0.5 to 100 fold the width of the channel (see abstract, column 1, lines 61-column 2, line 19, column 5, lines 40-45).

9. Regarding claim 10, the references Anazawa and Saaski disclose the claimed invention. Anazawa discloses the micro chemical device comprises a valve for which the pressure resistance is high and the channel cross sectional area does not depend on the fluid pressure (see abstract, column 2, line 19-22).

10. Regarding claim 20, the reference Anazawa discloses a micro chemical device with a valve function for which the pressure resistance is high and the channel cross sectional area does not depend on the fluid pressure. The micro chemical device is formed with a channel in one member that is bonded with another member as well as a cavity section formed as a portion of the channel in laminated members. The laminated members are from a flexible material with a specified tensile modulus of elasticity and compressing the cavity section from the outside of the member causes deformation in the flexible member. In an embodiment, the cavity is of a convex structure on the outer surface of the member and the flexible member may be constructed to be of a medium hard material surrounding the region of the cavity and of a soft material with a lower tensile modulus of elasticity at the corresponding position of the cavity section for deforming where the volume of the cavity section can be reduced in a reversible manner, regulating the flow rate in the device with ease. The flexible material in which the channels and cavity sections are made of can be of a thermoplastic polymer or a thermosetting polymer. The material used to make the softer portion of the layer may

also be cured products, which is interpreted by the examiner to be made of the medium hard material, for the more rigid sections of the layers (see abstract, column 1, lines 61-column 2, line 49, column 11, line 14-29). It is interpreted by the examiner that the members that are bonded together are bonded in a sealing manner. Furthermore, it is interpreted by the examiner that where the cavity section is of a convex structure formed on the flexible material to identify the corresponding cavity section is considered to be an engagement region. Anazawa does not disclose the member is made of an injection molding technique, but Saaski discloses a fluid handling device for handling continuous fluid flow rates in a device that comprises of a substrate made of a durable material in which the channel and cavities are made of such as molding (see abstract, column 24, lines 56-64). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the layer that covers the channels to be made of a well known manufacturing technique, such as injection molding so that the second part can be easily made of a single piece and be cost efficient.

11. Claims 5-6, 11-14 and 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anazawa and Saaski, and further in view of US Publication No. 2002/0081222 to Karp (herein referred 'Karp').

12. Regarding claims 5 and 11-12, the references Anazawa and Saaski disclose the claimed invention except for where the actuator is a membrane pump. Karp discloses a microfluidic fluid control device which includes a microfluidic pump mechanism having two unidirectional valves separated by an expandable reservoir that is formed in multiple layers of flexible membranes. The microfluidic pump may include an actuator

for moving the deformable membrane for moving fluid through the device where channel and/or chambers are defined in stencil layers of the device, where the channels and/or chamber portion have been cut out of the layer to permit fluid movement (see abstract, [0006-0008, 0019-0021]). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify to actuator to be a pump so that fluid is efficiently and effectively conveyed through the device.

13. Regarding claims 6 and 13-14, the reference Anazawa and Saaski disclose the claimed invention except for where the actuator is a metering valve. Karp disclose the microfluidic fluid control device includes a first inlet or channel with a valve seat disposed at a valve region and an outlet channel with a flexible member separating the channels, which are cut or removed from the substrates in which they reside in. The flexible member has an aperture aligned with the valve seat at the valve region that allowing fluid to flow in one direction, but blocked in the opposing direction (see abstract, [0006-0007, 0019]). This valve region that is disclosed by Karp is considered to be a metering valve allowing only an aliquot of fluid into the device through an inlet, but being blocked going the opposite direction. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the actuator to be a metering valve to only allow the small volume or a specified aliquot of fluid to be carried or conveyed throughout the device at a predetermined amount.

14. Regarding claims 18-19, the references Anazawa, Saaski and Karp disclose the claimed invention. Anazawa discloses the micro channel device has a channel formed between two members with a width from 1 to 1000 micrometers and a height from 1 to

1000 micrometers and a cavity section formed as a portion of the channel. In an embodiment, the cavity is of a convex structures on the outer surface of the member and the flexible member may be constructed to be of a medium hard material surrounding the region of the cavity and of a soft material with a lower tensile modulus of elasticity at the corresponding position of the cavity section for deforming, which is considered an engagement region. Furthermore, in an embodiment, the cavity section is from 0.5 to 100 fold the width of the channel (see abstract, column 1, lines 61-column 2, line 19, column 5, lines 40-45).

Conclusion

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTINE T. MUI whose telephone number is (571)270-3243. The examiner can normally be reached on Monday-Thursday 7-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on (571) 272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CTM

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